K113216

MAY - 3 2012

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter information

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Point of Care Products
2 Edgewater Drive
Norwood, MA 02062

Date summary prepared: May 1, 2012

Device Information

Proprietary Name: RAPIDPoint® 500 System

Common name: Lactate on blood gas system

Classification name: Lactic acid test system

Classification number: 21 CFR 862.1450, Class I, Exempt, KHP

Classification panel: Clinical Chemistry and Clinical Toxicology Devices

Predicate Device

Element	Predicate Device
Device Name	Lactate on RAPIDLab® 1200 Blood Gas System
Common Name	Lactate on blood gas system
510(k) Number	K031560
Manufacturer	Siemens Healthcare Diagnostics Limited

Device Description

Lactate (Lac) is a new parameter offered on the RAPIDPoint 500 (RP500) blood gas system. The RP500 system is a point-of-care and laboratory testing blood gas analyzer and currently measures a variety of parameters that have been previously cleared. Enabling the lactate measurement is accomplished through software design changes introduced in Software Version 2.0 and requires the use of a RAPIDPoint 500 Measurement Cartridge. No hardware or mechanical changes were needed.

510(k) Summary

Statement of Intended Use

The RAPIDPoint 500 system is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- Partial pressure of carbon dioxide
- Partial pressure of oxygen
- pH
- Sodium
- Potassium
- Ionized calcium
- Chloride
- Glucose
- Total hemoglobin and fractions: fO_2Hb, fCOHb, fMetHb, fHHb
- Neonatal bilirubin
- Lactate

This test system is intended for use in point of care or laboratory settings.

Indications for Use

Lactate. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Summary of Technological Characteristics

The integrated lactate sensor uses an amperometric method where the working electrode contains the enzyme lactate oxidase.

The lactate measurement is performed by a sensor that incorporates amperometric technology. The lactate biosensor is a complete electrochemical cell. A constant voltage, called a polarizing voltage, is maintained during analysis. In the lactate sensor, lactic acid from the sample interacts with the lactate oxidase on the surface of the measuring electrode to form pyruvic acid and hydrogen peroxide. The polarizing voltage is sufficient to cause oxidation of the hydrogen peroxide to oxygen. The loss of electrons in the oxidation of H_2O_2 creates a current flow that is directly proportional to the lactate concentration in the sample.

Assessment of Performance

Studies were conducted to demonstrate the performance of the RAPIDPoint 500 with lactate parameter and assess substantial equivalence against the Siemens Healthcare Diagnostics RAPIDLab 1265 (predicate device).

The lactate internal evaluation study entailed testing concentrations of lactate in whole blood across the reporting range. The lactate external evaluation study included testing at multiple point-of-care sites with intended use whole blood samples. Combining the results of the external evaluation for a total of over 140 samples, the coefficient of determination (r^2) value was within the acceptance criteria (>0.90). Specimens were

evaluated against the RAPIDLab 1265 predicate device and based on performance data analyzed, it was concluded that the predetermined acceptance criteria were met.

In addition, information on Software Development Life Cycle including software requirements specifications, risk management report, and overall verification and validation results were included to provide additional assurance of device performance.

Conclusion

In conclusion, the studies completed demonstrate that the RAPIDPoint® 500 System Lactate (Lac) Test is similar to the RAPIDLab 1265 predicate device in both Technological Characteristics and Intended Use. The data presented in the submission is a summary of internal evaluation, external clinical evaluation, and software development information. This information provides assurance that the RAPIDPoint 500 system measuring lactate has demonstrated substantial equivalence to the currently marketed Siemens Healthcare Diagnostics RAPIDLab 1265 predicate device across the reporting range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Steven Goldberg
Regulatory Affairs Specialist, Point Of Care
2 Edgewater Drive
Norwood, MA 02062

MAY - 3 2012

Re: k113216
Trade/Device Name: RAPIDPoint® 500 System
Regulation Number: 21 CFR § 862.1450
Regulation Name: Lactic acid test system
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR § 862.9 (c)(9)
Product Code: KHP
Dated: April 11, 2012
Received: April 12, 2012

Dear Mr. Goldberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113216

Device Name: RAPIDPoint® 500 System

Intended Use:

The RAPIDPoint 500 system is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- Partial pressure of carbon dioxide
- Partial pressure of oxygen
- pH
- Sodium
- Potassium
- Ionized calcium
- Chloride
- Glucose
- Total hemoglobin and fractions: fO_2Hb, fCOHb, fMetHb, fHHb
- Neonatal bilirubin
- Lactate

This test system is intended for use in point of care or laboratory settings.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)____K113216_____

The following list includes the **Indications for Use** information for each analyte measured on the Rapidpoint 500 System:

Lactate. A lactic acid test system is a device intended to measure lactic acid in whole blood. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Neonate Bilirubin. A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

pCO_2, $p0_2$, pH. Measurements of blood gases (pCO2, p02) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium. Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium. Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k)___K113216_____

Ionized calcium. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glucose. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Total hemoglobin. Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin. Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin. Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

Sulfhemoglobin. Sulfhemoglobin measurements are used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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